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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,414	01/06/2005	Raju Adhikari	07082.0020U1	5460
23859 7590 09/12/2007 NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER DICKINSON, PAUL W	
			ART UNIT 1609	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/520,414

Applicant(s)

ADHIKARI ET AL.

Examiner

Paul W. Dickinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, drawn to a star, dendrimer or hyper-branched prepolymer composition.

Group II, claim(s) 11-22, 26 drawn to a biocompatible, biodegradable polyurethane composition.

Group III, claim(s) 23-25, drawn to a process for the preparation of a biocompatible, biodegradable polyurethane composition.

Group IV, claim(s) 27-28, drawn to a method of treatment of damaged bone or cartilage.

The inventions listed as Groups I, II, III, and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I is a prepolymer composition comprising the reaction product of isocyanate and low molecular weight multifunctional core molecules having at least two functional groups that react with said isocyanate to form a urethane or urea groups. This element cannot be a special technical feature under PCT Rule 13.2 because the prepolymer composition is anticipated by Bennett et al (EP0837084;

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document provided by the International Bureau). Bennett et al discloses a prepolymer reaction product derived from the reaction of diNCO and multifunctional molecules having at least 2 functional groups (see pg 3, ln 21-34; Example 9) to form urethane groups.

The common technical feature of Groups II-IV are a biocompatible, biodegradable polyurethane composition comprising the reaction product of the prepolymer of Group I and linear star dendrimer or hyperbranched soft segment forming functional oligomers with degradable arms. This element cannot be a special technical feature under PCT Rule 13.2 because the composition is anticipated by Cohn et al (WO9902168; document provided by the International Bureau). Cohn et al discloses multi-block polymeric materials that comprise reaction products of C<sub>2-24</sub> diols and diisocyanates (see p 3, fourth full paragraph; p 25, second full paragraph) and linear star dendrimer segment to form functional oligomers with degradable arms (see p 8, first full paragraph).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

***Election***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If Applicant elects Invention I above, Applicant is further required to elect an isocyanate (First Election Requirement below), a low molecular weight multifunctional core (Second Election Requirement below), and whether or not the prepolymer composition further comprises biological and inorganic components (Third Election Requirement below).

If Applicant elects Invention II above, Applicant is further required to elect an isocyanate (First Election Requirement below), a low molecular weight multifunctional core (Second Election Requirement below), soft segment monomer(s) (Fourth Election Requirement below), and whether or not the biodegradable, biocompatible composition further comprises biological and inorganic components (Fifth Election Requirement below).

If Applicant elects Invention III above, Applicant is further required to elect an isocyanate (First Election Requirement below), a low molecular weight multifunctional core (Second Election Requirement below), and whether or not the process further comprises the step of reacting said prepolymer with a high molecular weight degradable polymer (Sixth Election Requirement below).

If Applicant elects Invention IV above, Applicant is further required to elect an isocyanate (First Election Requirement below), a low molecular weight multifunctional

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core (Second Election Requirement below), and soft segment monomer(s) (Fourth Election Requirement below).

#### First Election Requirement

Applicant is required to define the isocyanate with a particular species (see Claim 4-5, 8-10). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The isocyanates disclosed have different molecular structures and exhibit different chemical behaviors.

#### Second Election Requirement

Applicant is required to define the low molecular weight multifunctional core with a particular species (see Claim 2-3, 8-10). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The cores disclosed have different molecular structures and exhibit different chemical behaviors.

#### Third Election Requirement

Applicant is required to specify whether or not the prepolymer composition further comprises biological and inorganic components (see Claim 7). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1

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because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: A composition with biological and inorganic components will have a different bioactivity than a composition without said components.

#### Fourth Election Requirement

Applicant is required to elect one of the following soft segment monomers:

- (A) Lactides
- (B) Glycolides
- (C) Lactide/glycolides
- (D) Caprolactones
- (E) Propylene fumarates
- (F) Glycolic acid
- (G) Dioxanones
- (H) Anhydrides
- (I) Polyorthoesters
- (J) Phosphorylcholines
- (K) A combination of the above (If Applicant elects K, Applicant is required to specify the combination)
- (L) A soft segment monomer not listed above

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

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corresponding special technical features for the following reasons: The monomers have different molecular structures and exhibit different chemical behaviors.

#### Fifth Election Requirement

Applicant is required to specify whether or not the biodegradable, biocompatible composition further comprises biological and inorganic components (see Claim 22).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: A composition with biological and inorganic components will have a different bioactivity than a composition without said components.

#### Sixth Election Requirement

Applicant is required to specify whether or not the process further comprises the step of reacting said prepolymer with a high molecular weight degradable polymer (See Claim 25). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The step of reacting said prepolymer with a high molecular weight degradable polymer would produce a chemically different product than without said step.



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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

### ***Rejoinder Notice***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Inventorship Notice***

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul W. Dickinson whose telephone number is 571-270-3499. The examiner can normally be reached on Mon-Thur 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul W Dickinson  
Examiner  
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September 4, 2007

  
CECILIA TSANG  
SUPERVISORY PATENT EXAMINER